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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,734	07/13/2001	Yoshikatsu Kodama	011900-310	9324

7590 02/26/2003

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER
1614	9

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,734	Applicant(s) KODAMA ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election acknowledged

1. Acknowledgement is made of an election of Groups I (claims 1-2) with traverse. Applicant traversed on the ground that the invention I and II are not patentably distinct because they are not obvious variants. If the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. The traverse is partially accepted and the groups I-II will be examined together.

2. Upon the request for regrouping invention of groups I-II, the restriction is partially withdrawn and the invention of Groups I-II will be examined together. However, it is burden to examine all the entire groups because each group contains patentably distinct subject matter due to the reasons of the record(see paper no. 7) wherein a reference which anticipates the inventions I-II would not render the inventions III-IV obvious, absent ancillary art, and thus, it is undue burden for examiner to perform accurate and quality examination. Thus, the restriction requirement is properly maintained, and made FINAL.

Status of Application

1. Claims 1-6 are pending. The elected claims 1-4 are presented for the examination. Non-elected claims 5-6 are withdrawn from the consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al (EP0877032) in view of Kodama et al (EP1010434).

Kodama et al teach an inhibitor composition comprising a specific antibody obtained from eggs laid by hens which have been immunized against urease of Helicobacter pylori(Hp), and its utility as an pharmaceutical composition to inhibit adhesion of Hp to gastric mucosa in the Gastrointerstinal tract(GIT). The patent teaches that the said antibodies are effective for eradicating Hp adhered to gastric mucosa, see page 5, lines 13-15. It further teaches that the said antibody can be combined with a secondary active agent such as antacid for extra benefits added into the said antibody formulation, see page 5, lines 37.

Even though applicant's claims differ from Kodama's teaching because they specifically require an inhibitor of gastric acid secretion as a secondary agent, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kodamo's antacid substituted with an inhibitor of gastric acid secretion when Kodama(EP'032) is taken in view of Kodama(EP'434) because EP'434 teaches the inhibitor of gastric acid secretion as an effective additive wherein it could be combined with primary active agent(i.e. mucin) to enhance the therapeutic effectiveness. EP'434 patent(see paragraph 34-36) teaches the inhibitor of gastric acid

secretion as potent and effective secondary agents. Especially, EP '434 also contemplates adhesion inhibitor compound and the inhibitor of gastric acid secretion as most effective combination.

Thus, one would have been motivated to make such substitution because the substitution with the said inhibitor of gastric acid secretion would result in stronger inhibition of adhesion so that the effectiveness of treatment could be maximized as suggested in EP'434.

One would have been expected the successful result from the said substitution without undue experiment, although each patentee teaches different inhibitor compound(antibody vs. mucin), because the primary active agents(i.e.antibody and mucin) utilize very same biological mechanism(i.e. inhibiting adhesion of Hp to the receptor pf gastric mucosa(see EP'032 :page 3, line 10 and EP'434, paragraph 36) and the combinatory drug therapy by adding secondary agent utilizing different mechanism is commonly practiced and the enhancement of therapeutic efficacy is conventional wisdom, absent evidence to the contrary.

As to the rectied limitation(i.e. IgY antibody), it is noted that the said antibody(i.e. IgY) recited in the instant claims are inherent because Kodama's antibodies are also obtained from very same source, that is chicken egg laid by a hen which has immunized with an antigenically effective amount of an isolated Hp urease.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or

similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-2 and 6 of U.S. Patent No. 6,419,926 B2 in view of Kodama (EP 877032 A1 and 1010434 A2).

US'926 teaches an antibody composition used as an pharmaceutical preparation for treating diseases cause Hp using IgYantibody obtained from chicken egg laid by a hen which has immunized with an antigenically effective amount of an isolated Hp urease via inhibiting the adhesion of Hp urease into GI mucosa. It further teaches a combinatory drug therapy to enhance the therapeutic efficacy by adding a beneficial additive(e.g. lactic acid bacterium). However, it would have been obvious to any skill artisan at the time of the invention made to modify the substitution of secondary additives selected not only from microorganism but

also from other beneficial drugs including antacids, inhibitor of gastric acid secretion, GI mucosal protectants or digestive enzymes when US'926 is taken in view of EP'032 and Ep'434 because these references together teach that there are various additives can be used effectively to enhance the efficacy of primary active agent(e.g antibody or mucin) having inhibitory activity against Hp urease adhesion to GI mucosa. The teaching of EP'032 and EP'434 is mentioned immediately above in 103 rejection(supra). Thus, One would have been motivated to extend US'926 to include variety of secondary additives to obtain better results because the pharmacological activity of the secondary additives usually depends on different biological mechanism than the primary agent's mechanism(i.e. inhibition of adhesion), and thus, the additive effect or more can be obtained. Since the combinatory drug therapy is conventionally carried out in the art to improve the efficacy, any skill in the art would have selected most potent drug available in the art, that is the inhibitor of gastric acid secretion, with reasonable expectation of success without undue experiment.

Conclusion

1. No claim is allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where

this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
Art nit 1614